

VDH Interim Point-of-Care Antigen Testing Recommendations for Nursing Homes

Situation

The U.S. Department of Health and Human Services is distributing point-of-care (POC) testing devices (Quidel Sofia 2 instrument or the BD Veritor Plus system) to selected nursing homes in COVID-19 hotspot areas of the United States. Both of these machines test for the presence of SARS-CoV-2 antigens. Distribution will begin with nursing homes prioritized by CMS. VDH has developed these interim recommendations for nursing homes receiving these machines.

Background

<u>VDH Nursing Home Reopening Guidance</u> recommends testing should be performed using a viral diagnostic test. Recommendations differ slightly by the reopening phase, but in general include (1) testing symptomatic staff and residents, and (2) when positive cases are identified, testing close contacts or all staff and residents, depending on the likelihood of transmission occurring in the facility. Repeat testing is recommended to ensure transmission has either not occurred or has stopped following the implementation of infection prevention and control measures.

Positive results from antigen tests are highly accurate, but negative results do not rule out infection.

- The <u>Quidel Sofia 2 Factsheet for Healthcare Providers</u> states: "A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative test result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results, from patients with symptom onset beyond five days, should be treated as presumptive, and confirmation with a molecular assay, if necessary, for patient management, may be performed."
- The BD Veritor Plus Factsheet for Healthcare Providers includes similar language.
- Information in the <u>VDH Nursing Home Reopening Guidance FAQ</u> states negative antigen tests should be followed up with a confirmatory molecular test.
- False positive results can occur and are most likely in populations where the prevalence of SARS-CoV-2 infection is low.

Nursing homes performing POC tests must have an active CLIA Certificate of Waiver. More information can be found on the <u>VDH Office of Licensure and Certification website</u>.

At this time, turn around times (TAT) for results from molecular tests in Virginia are increasing due to the amount of tests being performed and other factors such as shortages of testing supplies. There is a need to find alternative solutions to molecular tests that will accomplish the same goal.

Assessment

Current VDH nursing home testing recommendations are limited to symptomatic individuals, close contacts of positive cases, or facility-wide testing in response to potential transmission in the facility. Results from these situations impact patient management. If an antigen test is performed and the result is negative, it should be followed up by a confirmatory molecular test. Testing recommendations include repeat testing in the majority of

Last Updated: 8/6/2020



nursing home situations to ensure transmission has not occurred. It would be reasonable to perform antigen tests on the first round of testing, while the second round of testing could be a molecular test. This would contribute to faster results for nursing homes using a POC antigen test and would decrease the amount of molecular tests being performed. The repeat molecular test would also serve as the confirmatory test necessary for patient management.

Recommendations

- 1. Table 1 describes the role of an antigen test based on current VDH nursing home testing recommendations; a negative antigen test should be followed up with a confirmatory molecular test.
- 2. A negative antigen test should not be the sole basis used to determine if a patient can be taken off transmission-based precautions.
- 3. Nursing homes that perform POC tests will be responsible for reporting results to public health.
- 4. Suspected and confirmed outbreaks are required to be reported rapidly to the local health department. If an outbreak is identified through antigen testing, please submit 2-5 specimens for molecular testing at the state public health laboratory. Coordinate with your local health district for specimen submission.

Table 1Note: VDH testing recommendations are simplified and summarized. More information can be found <u>here</u>.

Phase	Testing Scenario	Testing Technology Recommended
I	Initial baseline testing of all residents and staff with repeat testing of all residents and all staff, ideally within a week. Weekly testing can stop after 14 days of no new positive cases.	Initial baseline testing can be molecular or antigen. Repeat weekly^ testing should be molecular*.
1, 11, 111	Testing symptomatic residents or staff.	Molecular; Depending on known TAT of molecular tests, a rapid antigen test could be used. Negative antigen results should be confirmed by a molecular test, especially when symptom onset is more than five days after the antigen test specimen was collected.
ı	Testing all staff and all residents in response to a positive staff member or NH-onset case (first round) with repeat testing of all residents and all staff, ideally within a week. Weekly testing can stop after 14 days (two rounds) of no new positive cases.	First round of testing can be molecular or antigen. Repeat weekly^ testing should be molecular*.
1, 11, 111	Testing close contacts in response to a non-NH onset case. If additional cases are found, repeat testing of all staff and all residents, ideally within a week. Weekly testing can stop after 14 days (two rounds) of no new positive cases.	Molecular or antigen; negative antigen results should be confirmed by a molecular test. If additional cases are found, the first round of testing can be molecular or antigen. Repeat weekly^ testing should be molecular*.
11, 111	Testing close contacts in response to identification of a staff case with repeat testing of close contacts, ideally	First round of testing can be molecular or antigen. Repeat weekly testing should be

Last Updated: 8/6/2020



within a week. Weekly testing can stop after 14 days (two rounds) of no new positive cases.	molecular*.
---------------------------------------------------------------------------------------------	-------------

Alf an antigen test is performed for the first round of testing, the second round of testing by a molecular test can occur 3-7 days after. Waiting a week to confirm a negative antigen test result may not be warranted.

*Repeat testing by molecular methods would confirm negative findings from the first round of antigen testing.

Last Updated: 8/6/2020